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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/446,783	05/16/2000	NEIL P. DESAI	VPHAR1460-2	2878
30542	7590	07/12/2005	EXAMINER	
FOLEY & LARDNER P.O. BOX 80278 SAN DIEGO, CA 92138-0278			HARTLEY, MICHAEL G	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/446,783

Applicant(s)

DESAI ET AL.

Examiner

Michael G. Hartley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 73-75, 103-105 and 122-133 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 73-75, 103-105 and 122-133 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/28/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Response to Amendment

The amendment filed 4/15/2005 has been entered.

Response to Arguments

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 73, 103, 108 and 122-132 are rejected under 35 U.S.C. 102(e) as being anticipated by Violante (US 5,741,522), for the reasons set forth in the office action mailed 10/15/2004.

Applicant's arguments filed 4/15/2005 have been fully considered but they are not persuasive.

Applicant asserts that claim 73 distinguishes over Violante at least by requiring a dry powder or liquid formulation of a water insoluble drug and at least one protein.

This is not found persuasive because Violante discloses an article of manufacture comprising non-crystalline (i.e., amorphous) ultra-small particles of a drug, which are coated with a protein, see abstract and example III. In example III, IDE porous (amorphous, solid) particles are coated with human serum albumin (note: the IDE particles are within the scope of "drug" nanoparticles, as IDE is a CT contrast agent, see column 7, lines 43+). Violante also discloses that the particles include various drugs, many of which are water insoluble (i.e., wafarin, etc.), see column 9 and column 11, lines 45+. The above argument fails to specifically discuss what is missing from Violante.

Applicant asserts that Violante is different from the claimed invention as it is drawn to water soluble, iodinated contrast agents that contain gaseous microbubbles.

This is not found persuasive because Violante clearly discloses particles as claimed that include a water insoluble drug (e.g., wafarin, etc.), see column 9. Further the iodinated contrast agent may be water insoluble, see column 6, lines 60+. The particles form microbubbles when suspended in a liquid.

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The claimed particles do not exclude particles which may form microbubbles. This argument fails to provide a clear difference between the claimed invention and Violante, other than conclusionary statements that they are different. What specifically is missing from Violante is unclear.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 73, 74, 104 and 133 are rejected under 35 U.S.C. 103(a) as being unpatentable over Violante (US 5,741,522) in view of Unger (US 6,143,276), for the reasons set forth in the office action mailed 10/15/2004.

Applicant's arguments filed 4/15/2005 have been fully considered but they are not persuasive.

Applicant repeats the arguments for Violante and asserts there is no motivation to combine the references.

The argument for Violante is set forth above. Violante teaches that various drugs, may be included in the particles, including anti-cancer agents. Violante and Unger are in the same field of endeavor, e.g., ultrasound contrast agents and drug delivery particles. Violante only fails to disclose the same drugs, e.g., anticancer drug taxol, as claimed. Unger discloses particles in the same field of endeavor and teaches that such particles may be used as carries for various equivalent drugs, including those claimed, e.g., that various drugs may be employed in the nanospheres, including hormones, cyclosporin, taxol, anesthetics, etc., see columns 36-37. The motivation to combine comes from that the particles are in the same field of endeavor and Unger teaches that various drugs, e.g., anticancer drugs, such as, taxol, as claimed, may be delivery in such particles to optimize the type of treatment required.

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For example, known drugs such as taxol treat specific cancers. Unger teaches these drugs benefit by being in carriers which are similar to those of Violante.

Applicant also asserts that a combination of Violante and Unger would not arrive at the instant invention.

This is not found persuasive because substituting the therapeutic agent (e.g., anticancer drug) of Violante in such particles, such as, taxol, as disclosed by Unger, would arrive at the instant invention. Applicant's assertion seems to narrowly conclude what is disclosed by the prior art.

Claim 105 is rejected under 35 U.S.C. 103(a) as being unpatentable over Violante (US 5,741,522) in view of Unger (US 6,143,276), as applied to claims 73, 74, 104 and 133 above, and further in view of Jones (US 5,731,355), for the reasons set forth in the office action mailed 10/15/2004.

Applicant's arguments filed 4/15/2005 have been fully considered but they are not persuasive.

Jones is only being relied upon to teach that propofol is a well-known and highly successful anesthetic, see column 1. Both Violante and Unger teach that various equivalent drugs benefit by being incorporated into particles carriers, such as, albumin particles. The skilled artisan would have been motivated to use various equivalent and known drugs in the carriers disclosed by Violante, such as, propofol as disclosed by Jones to optimize the particles for the treatment desired. The use of propofol as the drug in the particles of Violante would arrive at the instant claims.

Claims 73-75, 103-104, 108 and 122-133 are rejected under 35 U.S.C. 102(b) as being anticipated by Desai (US 5,439,686) in view of Westesen (US 6,197,349), for the reasons set forth in the office action mailed 10/15/2004.

Applicant's arguments filed 4/15/2005 have been fully considered but they are not persuasive.

Applicant asserts that Desai does not disclose the claimed particles, but fails to specifically reason what is missing from Desai.

Applicant asserts that there is no motivation to combine Desai and Westesen.

This is not found persuasive because these references are in the same field of endeavor, e.g., drug-delivery particles. Desai discloses all the limitations as claimed, but is silent as to whether or not the drug nanoparticles are amorphous.

Westesen teaches drug nanoparticles for the delivery of various drugs, taxol, etc., see abstract and column 13. Westesen also teaches that the drug nanoparticles should be amorphous because an amorphous state provides a higher solubility and a faster dissolution of the drug, see column 5, lines 45-57. This is clear motivation to combine. They are in the same field of endeavor and Westesen teaches that drug nanoparticles that the amorphous state provides a higher solubility and a faster dissolution of the drug.

Applicant also asserts that the combination would not arrive at the invention.

This is not found persuasive because using amorphous drug in the particles of Desai would arrive at the instant invention. A combination of references does not require that every disclosed embodiment of the secondary reference must be used in the primary reference as appears to be asserted in the arguments.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons set forth in the office action mailed 10/15/2004.

Applicant's arguments filed 4/15/2005 have been fully considered but they are not persuasive.

Applicant asserts that the albumin coating is not within the scope of surfactant, as set forth in claim 75.

This is not found persuasive because a surfactant is defined as a surface-active agent, which clearly encompasses albumin. Clearly a coating on a drug is within the scope of a surface-active agent.

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A text search of the terms "surfactant" and "albumin" the same paragraph resulted in over 1000 hits in the patent literature alone. A brief examination of these hits revealed that albumin is often defined as a surfactant. For example, see US 3,911,138 which states "naturally occurring surfactants such as albumin" (see col. 8, lines 5-9) or US 4,914,084 which states "mixtures of the above surfactants, such as, albumin" (col. 6, lines 19-24) or US 4,920,061 which states "Suitable surfactants include human serum albumin" (col. 6, lines 4-10), to mention just a few. In sum, the recitation of albumin (especially as a coating as set forth in the instant claims), is clearly within the scope of the term surfactant.

Conclusion

No claims are allowed at this time.

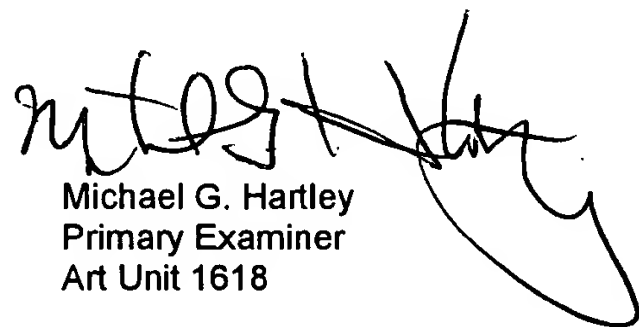
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (571) 272-0616. The examiner can normally be reached on M-Tu and Th-F, 7:30-4, Telework on Wed.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael G. Hartley
Primary Examiner
Art Unit 1618

6/27/2005